REMARKS

Claims 1-14 are pending in the application.

The specification has been amended to correct two typographical errors.

Claims 1-14 have been amended to render their meaning more clear.

Fig. 1 has been amended by replacement sheet to add the legend "Fig. 1".

No new matter has been added by these amendments.

I. Objection to the Drawings

The Examiner has objected to the drawing sheet on the ground that it does not contain the reference "Fig. 1." The application has been amended by the addition of the replacement sheet drawing which contains the reference. No new matter is added by the change to the drawing.

In view of the foregoing, it is submitted that the Examiner's objection to the drawing is no longer applicable. Reconsideration and withdrawal of the rejection is requested.

II. Objection to Specification

The Examiner has object to the specification on the grounds that it contains a misspelled word in paragraph 12. Paragraph 12 has been amended to correct the spelling error.

It is submitted that the Examiner's objection is no longer applicable. Its reconsideration and withdrawal is respectfully requested.

III. Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 1-14 under 35 U.S.C. § 112, second paragraph asserting that such claims lack clarity. The applicants do not agree; however, in the interest of facilitating the progress of the application the applicants have amended the claims to provide additional clarification.

Claim 1:

As is apparent from the claims as filed and in the specification (*e.g.*, at paragraph [0019]), the language "which may be coupled thereto" refers to the relationship of the spacer 3 and the coupling device 4. Claim12 has been amended to better clarify that the spacer (3)-may be coupled to the extracorporal coupling device (4).

Claim 14:

As is apparent from the claim itself and the specification (*e.g.*, at paragraph [0020]), the shoulder (10) is formed on the coupling element (6) of the extracorporal coupling device (4). The drawing does not appear to show an extra "unlabeled" coupling element on which the shoulder is located, as the Examiner seems to suggest.

Claims 2-13:

The rejections of dependent claims 2-13 are addressed above as each of these claims depends from claim 1or 14 directly or indirectly.

In view of the foregoing, it is submitted that the rejection under 35 U.S.C. § 112, second paragraph, is overcome. Reconsideration and withdrawal of the rejections is respectfully requested.

IV. Rejection Under 35 U.S.C. § 102(b)

The Examiner has rejected claims 1, 3 and 5 under 35 U.S.C. § 102(b) as being anticipated by the disclosure of U.S. Patent Application Publication No. 2004/0068324 A1 Grundei ("Grundei"). The Examiner has argued that Grundi discloses all elements of the invention relying on Grundei at paragraph 5, lines 6-11 and 52-57. The Examiner has stated that Grundei teaches that the "bush widens out significantly from the end thereof facing the extracorporal direction to the end thereof facing the intracorporal direction (cone 15 widens in the intracorporal direction)", but has provided no support for this statement.

The Examiner further argues that the surface described at page 3, paragraph 34, line 33-35, has an antibacterial effect and that page 3, paragraph 34, lines 33-35 describe plating which, the Examiner equates to the recitation in claim 5 of a bush surface that is plated with titanium.

The applicants traverse the rejection.

Grundei teaches subcutaneous intramuscular support for a ridged transcutaneous implant. Grundei teaches that the objective of the Grundei invention is to further develop a subcutaneous muscular support that is characterized by increased safety against infection of the implant at the site of penetration . As can be seen in Figure 1 of Grundei, the implant includes an implant tube that is inserted in a femur stump (11). The implant is closed off distally by a metal sleeve (12) which has a proximal peripheral flange (13) which encloses the femur stump (11). Inside the metal sleeve (12) is formed a conical clamping sleeve (14) that is provided to produce a conical clamp connection with intermediate piece (3) which is designed as a double cone. The intermediate piece (3) has a cylindrical center section (9) unto which the bushing (5) is shrunk. Another cone (15) lies distally adjacent to the center section (9) to produce a conical clamp connection to a conical clamp sleeve (17) in an adapter of the extracorporal device (4). The Examiner contends that the cone (15) corresponds to the bush (5) in the current convention.

The disclosure of Grundei does not disclose all elements of the invention. Claim 1 recites the mounting for an implant that includes a spacer which is embodied as a rigid bush sealed in the intracorporal direction wherein the bush widens out significantly from the end thereof facing the extracorporal direction to the end thereof facing the intracorporal direction and comprises a smooth surface.

The support disclosing Grundei does not teach or suggest at least two elements of the invention, Grundei does not teach or suggest a bush as recited in the instant claim. The bush of the invention is a rigid bush that is sealed in the intracorporal direction and it widens out significantly from the end facing the corporal direction and facing the intracorporal direction as is noted in the specification, the bush contacts the soft tissue once mounting is applied. *See, e.g.*, Paragraph [0006] ("The soft tissue surrounding the spacer, specifically the bush, atrophy onto the bush, and significantly more so in the area of the bush facing the intracoporal direction than in the part facing the extracorporal direction.") Due to the special design of the bush in the invention, a sufficient champagne cork effect of the bush in relation to the seal is achieved.

In contrast the cone (15), which the Examiner alleges as corresponding to the bush (5) of the invention, is a connection device which lies distally adjacent to the center section (9) to produce a conical clamp connection to a conical clamping sleeve in an adapter of extracorporal coupling device. Thus, cone (15) is surrounded by a conical clamping (17) and there is no contact of the cone (15) with the soft tissue. Accordingly, neither cone (15) nor the support of the Grundei disclosure has any sealing function in the sense of the present bush (15).

Second, there is simply no disclosure in any of Grundei that the surface of cone (15), is smooth, the Examiner supports his assumption that the cone (15) is smooth by relying on the disclosure of Figure 1. However, Figure 1 is a cross-section of the support and no surface structure of cone (5) is shown.

Accordingly, because the disclosure of Grundei does not teach each element of the invention, it does not anticipate it. Reconsideration and allowance of the claims is respectfully requested.

V. Rejections Under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-14 as obvious under 35 U.S.C. § 103 (a) iv view of Grundei, either alone or in combination with one or more additional references. Specifically:

(a) claim 2 is rejected as obvious over the disclosure of Grundei as modified by the Examiner;

(b) claims 4,6,7,8,14 are rejected as obvious over the disclosure of Grundei combined with U.S. Patent No. 4,615,705 to Scales ("Scales");

(c) claims 9 and 10 are rejected as obvious over the disclosure of Grundei combined with Scales and U.S. Patent Application Publication No. 2003/0171825 A1 to Blunn ("Blunn");

(d) claim 11 is rejected as obvious as over the disclosure of Grudei combined with Scales and U.S. Patent No. 5,888,215 to Roos et al. ("Roos");

(e) claim 12 is rejected as obvious as over the disclosure of Grudei combined with Scales and Cementless Titanium Tapered-Wedge Femoral Stem" by Marshall et al. ("Marshall"); and

(f) claim 13 is rejected as obvious as over the disclosure of Grundei combined with Scales and WO 99/64491 to Spaans et al. ("Spaans").

The applicant traverses each of these rejections.

A summary of the disclosure of Grundei is provided above. As noted, Grundei is silent with respect to the disclosure of a rigid bush that is sealed in the intracorporal direction and it widens out significantly from the end facing the corporal direction and facing the intracorporal and with respect to a rigid bush that has a smooth surface as is recited in the claims.

Scales teaches surgical implants that are rendered antimicrobial by a bioerodible metallic silver component especially a surface coating which provides *in vivo* a sustained release of silver ions in a concentration sufficient to provide a localized antimicrobial effect but insufficient to be the cause of significant damage to connective tissue.

Blunn teaches the use of a surface treatment transcutaneous prosthesis that encourages osseous integration such as hydroxyapatite (which is a hydrated calcium phosphate). Blunn does not teach or suggest that hyrdoxyapatite or calcium phosphate should be used to prevent infection between the skin and a prosthesis.

Roos teaches a lower extremity prosthesis containing a skeleton screw. Roos teaches that the selection of material in the skeleton screw is "critical" and that it has been previously known that pure titanium is superior as components of pure titanium quickly oxidize on the surface so there is formed a layer of titanium peroxide which results in a barrier function against chronic tissue inflammation and becomes incorporated into the cells of the surrounding tissues thereby counteracting repelling phenomena.

Marshall discloses a clinical and radiographic analysis of the titanium tapered wedge from a component with a proximal process spray porous coating. Contrary to the Examiner's representation, Marshall teaches that circumferential porous coating contributes to long term bone ingrowth and that, in Marshall's specific study, use of a titanium tapered wedge design with a plasma-spray porous coating had an excellent 10-15 clinical and radiographic results with spot welds in 99% of cases an adaptive bone remodeling indicative of bony fixation.

Spaans teaches a specific type of polyurethane that is reportedly suitable for biomedical applications, including implants.

Claim 2:

The Examiner argues that Grundei teaches all elements of claim 2 except for the ratio of the base edge of the bush at its extracorporally oriented end to the length of its extracorporally oriented end. Grundei as modified does not render the claimed invention obvious, for Grundei, even in its modified form proposed by the Examiner does not teach or suggest each element of the invention. Specifically, as articulated above, Grundei does not teach or suggest a bush either having a structure or located within the support as is recited in the claims. Additionally, a person of skill in the art would have had no motivation to modify Grundei to arrive at the length ratios recited in claim 2. Grundei does not teach or suggest a champagne type cork seal as is formed by the components recited in the claim. Thus, a person of skill would have had no reason to make the modification proposed by the Examiner.

Claims 4, 6, 7, 8, and 14

The Examiner has rejected claims 2, 4, 6, 7, 8 and 14 as obvious under 35 U.S.C. § 103(a) over the disclosure Grundei combined with U.S. Patent No. 4,615,705 to Scales ("Scales"). The Examiner argues that Grundei discloses all elements of the invention except for an adaptation tube that has an antibacterial effect (claim 4) of plated silver (claims 7 and 8) and the location of the tube relative to a shoulder (claim 14).

Grundei combined with Scales does not render the claims obvious. The combination does not teach or suggest each element of the invention. Specifically, as articulated above, Grundei does not teach or suggest a bush either having a structure or located within the support as is recited in the claims. Moreover the Examiner has failed to show why a person of skill in the art would have made the combination; no such reason exists. Scales is directed to surgical implants and sutures, especially bone pins, bone plates, and artificial joints, not transcutaneous implants as are disclosed in Grundei. Accordingly, a person of skill in the art would not have been motivated to make the combination proposed by the Examiner.

Claims 9 and 10:

The Examiner has rejected claims 9 and 10 under 34 U.S.C. § 103(a) as obvious in view of the combination of Grundei considered in view of Scales further in view of U.S. Patent Application Publication No. 2003/0171825 A1 to Blunn ("Blunn"). The Examiner contends that

Grundei/Scales combination teaches a mounting according to claim 6 and that both teach a structure where the adaptation tube is constructed out of a material whose outer wall is coated with hydroxyapatite or calcium phosphate. Blunn, the Examiner contends, teaches that it is known that the hydroxyapatite or calcium phosphate can be used to prevent infection between the skin and prosthesis and encourages osseous integration. Thus, the Examiner reasons that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the use of hyroxyapatite or calcium phosphate to coat the outer wall of the adaption tube in the region of tissue contact in order to prevent infection between the skin and the prosthesis and encourage osseous integration as taught by Blunn.

The combination of Grundei, Scales and Blunn does not render the claimed invention obvious for it does not teach or suggest every element of the claims. Specifically, as discussed above, the combination of Grundei, Scales and Blunn is missing a disclosure of a bush widened out significantly from the end facing the extracorporal direction to the end facing the intracorporal direction and which comprises a smooth surface. Blunn does not address these points and therefore does not remedy the deficiency of Grundei and Scales; therefore the Grundei/Scales/Blunn combination as a whole does not teach or suggest at these two elements of the invention.

Moreover, a person of skill in the art would not have been motivated to make the combination suggested by the Examiner. Contrary to the Examiner's assertion there is no teaching in Blunn that hydroxyapatite or calcium phosphate is germicidal or antibacterial. Thus a person of skill would not have been motivated to make the combination as proposed by the Examiner.

Claims 11

The Examiner has rejected claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Grundei taken in view of Scales further considered in view of U.S. Patent No. 5,888,215 to Roos et al. ("Roos"). The Examiner reasons that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used titanium for the construction of the adaptation tube in the region of tissue contact in order to yield a barrier function against chronic tissue inflammation as taught by Roos. First, for the reasons given above, Grundei does not teach or suggest all elements of the invention. Moreover, a person of skill in the art would not

have had any reason to combine Grundei and Roos to arrive at the invention. Roos teaches that titanium is a material that can be used in the skeleton screw, *i.e.*, the screw in the Roos device by which the prosthesis is screwed into/or integrated within the bone. A person with skill in the art would not have been motivated to select the titanium material based upon the disclosure of Roos and apply it to the outer wall of the adaptation tube, which is not the device by which the intramuscular mounting of the invention is attached to the bone stump. For at least these reasons, a person of skill would not have made the combination suggested by the Examiner.

Claims 12

The Examiner has rejected claim 12 under 35 U.S.C. § 103(a) as being unpatentable under Grundei considered in view of Scales and further in view of the journal article "Cementless Titanium Tapered-Wedge Femoral Stem" by Marshall et al. ("Marshall"). The Examiner agrees that neither Grundei nor Scales teaches a device wherein the adaptation tube is constructed out of a material whose outer wall is coated with a plasma titanium spray. Marshall, according to the Examiner, teaches that it is well known that plasma titanium sprays can be used to contribute to long term bone, *i.e.*, tissue ingrowth. Thus, the Examiner reasons that it would have been obvious to one of ordinary skill in the art at the time of the invention to use titanium coated sprays for coating the outer wall of the titanium tube in the region of tissue contact in order to contribute to long term tissue growth as implicitly taught by Marshall.

The Grundei, Scales and Marshall combination does not teach or suggest each element of the invention as claimed nor would a person of skill in the art have had any reason to make the combination. First, as detailed above Grundei is lacking in at least two elements of the invention. Nether Scales nor Marshall remedies this deficiency. Moreover, no reasons exists that would have caused a person of skill to make the combination suggested by the Examiner. Marshall's disclosures are directed to a very specific type of device, which neither Grundei nor Scales addresses. A person of skill in the art would have had no reason to believe that the benefits achieved in Marshall could be achieved in an altogether different device. For at least this reason, a person of skill would have had no reason to make the combination proposed by the Examiner.

Claim 13

The Examiner has rejected claim under 35 U.S.C. § 103(a) as being unpatentable over Grundei combined with Scales and considered in view of WO 99/64491 to Spaans et al. ("Spaans"). The Examiner concedes that neither Grundei nor Scales teaches a device wherein the adaptation tube constructed of polyurethane. To remedy this deficiency, the Examiner applies the teaching of Spaans which allegedly reports that it is known that polyurethane is a biomedical material that can be processed into porous shaped bodies, *i.e.*, "as implants" and has good mechanical properties. Thus, the Examiner argues that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the polyurethane for the construction of the adaptation tube because it is a biomedical material that can be processed into porous shaped bodies such as implants. Moreover, the Examiner asserts that the use of polyurethane is nothing more than the selection of the known material based on its suitability for its intended use.

The combination of Grundei, Scales and Spaans does not render the claimed invention obvious. As explained above, the disclosure of Grundei is lacking at least two elements of the invention as claimed. Neither Scales nor Spaans remedies this deficiency. Additionally, a person of skill in the art would not have made the combination suggested by the Examiner. Grundei, Scales and Spaans each disclose different supports and/or implants. A person of skill therefore would not have been motivated to make the proposed combination.

It view of the foregoing, it is submitted that the Examiner's obviousness rejection has been overcome. Reconsideration and allowance of the claims at the earliest opportunity is respectfully requested.

CONCLUSION

At page 10-12 of this Office Action, the Examiner has listed the prior art made of record and made comments reportedly summarizing each period. The applicant wishes to clarify that they have not reviewed the Examiner's characterizations of the prior art of the teachings in each of those documents and accordingly do not agree or disagree with the Examiner's summaries.

In view of the forgoing, it is submitted that the applicant has demonstrated the patentability of all claims 1-14 over the cited art. Reconsideration and allowance of claims at the earliest opportunity is respectfully requested.

Respectfully submitted,

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Enclosure: Replacement Sheet – Fig. 1